REMARKS

The Applicants request the entry of an amendment to Claims 21, 26, 29, and 34.

In Claims 21 and 29 the Applicants are adding the phrase "whereby the carrier material is selected from the group consisting of starch, saccharose, lactose, and sugar". The basis for this amendment can be found on page 18, line 15.

The Applicants also are amending Claim 29 to remove the phrase "with the proviso that said veterinary active ingredient are not mixed with surfactants prior to coating said carrier material" and to add the phrase "mixing at least one veterinary active ingredient with a solvent". The basis for the phrase concerning the mixing of the veterinary active ingredient with a solvent is found on page 18, lines 18-23.

In Claims 26 and 34, the Applicants are deleting the word "lysed", the basis of this amendment can be found on page 20, line 32.

The Applicants also request the cancellation of Claims 23 and 31.

No new matter is being added.

35 U.S.C. § 112, first paragraph

The Examiner rejected Claims 29-35 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Examiner felt that the claims contained subject matter which is not described in the Specification in such a way as to convey to one of ordinary skill in the art that the Applicants were in possession of the claimed invention. Specifically, the phrase "with the proviso that said veterinary active ingredient are not mixed with surfactants prior to coating said carrier material" is not in the Specification, according to the Examiner.

The Applicant disagree with the Examiner's characterization of the added phrase. However, in order to move the claims toward allowance, the Applicants are requesting the deletion of this phrase.

The Applicants are also requesting the addition of the phrase "mixing at least one veterinary active ingredient with a solvent" to Claim 29. The Applicants believe that this phrase accomplishes the goal of indicating that one does not mix the veterinary active ingredient with a surfactant prior to coating the carrier material.

35 U.S.C. § 102(b)

The Examiner rejected Claims 21-24 and 29-32 under 35 U.S.C. § 102(b) as being anticipated by McTeigue et al. (U.S. Patent 6,149,943). The Examiner wrote that McTeigue et al. discloses a particle tablet containing cellulose (substrate) and coated particles containing the pharmaceutically active ingredient and polymer having the mean particle diameter of about 160

to 220 microns where the carrier is coated with an active agent which, in turn, is coated with a taste masking layer. The Examiner indicated that the cellulose, as the substrate, taught by McTeigue et al. could be an animal feed.

The Examiner argued that Claim 21 "does not specify what compounds come under animal feed. Therefore, cellulose taught by McTeigue et al is deemed to come under this category."

The Applicants respectfully disagree with the Examiner's understanding of McTeigue et al. and with the Examiner's conclusion about what compounds can be considered animal feed.

Concerning the teaching of McTeigue et al., McTeigue et al. uses **microcrystalline cellulose** as the seed core on which the active ingredient is applied. The microcrystalline cellulose coated with the active ingredient becomes the coated particles on which a taste masking layer is applied. McTeigue et al. does not disclose using **cellulose** as a substrate (and by "substrate" it is the term as defined by the Applicants in the Specification).

Example 6 in McTeigue et al. at the bottom of Column 8 through the middle of Column 9 describes the manufacture of a "chewable tablet". This chewable tablet contains "microcrystalline cellulose" as an inactive ingredient in the table at the top of Column 9. This microcrystalline cellulose is the seed core for the coated particles. The microcrystalline cellulose is found in the coated particles (CA/PVP coated acetaminophen; CA/E100 coated pseudoephedrine hydrochloride, CA/E100 coated diphenhydramine hydrochloride). The table in Example 6 does not list "cellulose". In addition the table in Example 6 fails to list a substrate that is a known animal feed which is an element of Claim 21.

Applicants are amending Claims 21 and 29 in such a manner to as make this rejection moot. In Claims 21 and 29, the Applicants are defining Applicants' carrier material as being selected from the group consisting of starch, saccharose, lactose, and sugar. Unlike McTeigue et al., the Applicants are not using microcellulose as a "core" onto which the veterinary active ingredient is applied. So, McTeigue et al. no longer qualifies as describing each and every element of the claimed invention.

The Applicants kindly request that the Examiner withdraw this rejection under § 102(b).

35 U.S.C. § 103(a)

The Examiner rejected Claims 25, 27, 33, 35, and 36 under 35 U.S.C. § 103(a) as being unpatentable over McTeigue et al. (U.S. Patent 6,149,943) in the top paragraph of page 3. The Examiner stated that McTeigue et al. does not teach lysed yeast and benazepril. However, McTeigue et al. teaches generic pharmaceuticals, and one of ordinary skill in the art would use the compositions of McTeigue et al. for any pharmaceutical including the claimed class of compounds with reasonable expectations of success. The Examiner also felt that while McTeigue et al. does not teach vitamins as additives, McTeigue et al. teaches vitamins on column 3, line 65.

In the last sentence at the end of this paragraph, the Examiner wrote "However, Patel et al. and Kitamura et al. disclose what McTeigue et al. lacks." However, this paragraph indicates that the basis of the rejection is McTeigue "**alone**". The Applicants believe that this sentence was accidentally included in the paragraph which deals with McTeigue et al. only as a § 103(a) prior art reference. Thus, the Applicants will not comment on this sentence further.

Furthermore, the Applicants respectfully point out that Claims 25, 27, 33, 35, and 36 do not have the limitation of "lysed yeast". As such, the Applicants believe that the Examiner accidentally included this phrase in this portion of the Office Action. The Applicants will not comment on this phrase in relations to the use of McTeigue et al. alone as prior art any further.

The Applicants also point out the Claim 28 has the limitation of benazepril, similar to Claim 36. As such, the Applicants believe that the Examiner meant to include Claim 28 with this rejection, rather than with the rejection involving Patel et al., Gasson et al., and Kitamura et al., see below.

The Applicants respectfully disagree with the Examiner's rejection under 103(a) citing McTeigue et al. alone. As discussed above, McTeigue et al. fails to describe at least one element of Claims 21 and 29, namely the limitation of animal feed. One of ordinary skill in the art would not be able to overcome the deficiency by the addition of pharmaceuticals and/or vitamins. The Applicants are not agreeing that the addition of vitamins or pharmaceuticals is obvious in light of McTeigue et al. Rather, the Applicants need not even discuss this issue because McTeigue et al. combined with the knowledge of people of ordinary skill in the art does not overcome McTeigue et al.'s deficiency (as described above). The additional limitation of vitamins, anti-parasitic agents, anti-bacterial agents, anti-viral agents, neurotropic agents, and benazepril in Claims 25, 27, 28, 33, 35, and 36 are not relevant if the independent claims, Claims 21 and 29 are patentable.

Furthermore, with the amendments to Claims 21 and 29, McTeigue et al. fails to qualify as prior art under § 103(a). In Column 2, line 54 through Column 3, line 14, McTeigue et al. states that the microcrystalline must be porous and have an irregular shape on the surface. "The irregular surface morphology provides porosity and allows the pharmaceutically active ingredient to be applied to the surface and to be adhered or retained on the surface..." (Column 2, lines 58-60). McTeigue et al. stresses the importance of the microcrystalline irregular surface shape and porosity.

In Column 3, lines 15-24, McTeigue et al. states that in the past, it was widely believed that smooth spherical particles were best suited for being the core material onto which the active ingredient is coated. According to McTeigue et al, sugar spheres are one such example of such material. U.S. Patents 5,384,130 (Kamada) and 5,505,983 (Kamada), both of which are cited in McTeigue et al., state that the core material can be sugar, lactose, and starch. McTeigue et al. teaches that one should NOT use such substances for the core material. Thus, McTeigue et al.

teaches away from the invention claimed in Claims 21 and 29. As such, McTeigue et al. alone cannot make Claims 25, 27, 33, 35, and 36 obvious.

The Examiner rejected Claims 26, 28, and 34 under 35 U.S.C. § 103(a) as being unpatentable over McTeigue et al. (U.S. Patent 6,149,943) in view of Patel et al. (WO 01/37808), Gasson et al. (U.S. Patent 5,763,251), and Kitamura et al. (U.S. Patent 3,917,510). [As discussed above, the Applicants believe that the Examiner meant Claims 26 and 34 only in this part of the rejection in light of the fact that both Claims 26 and 34 include the limitation of lysed yeast and Claim 28 includes the limitation of benazepril.]

Before discussing the arguments set forth, the Applicants respectfully point out an apparent language issue surrounding the various words in the various documents. Patel et al. discloses "solid carrier" which is made up of a "substrate" and an "encapsulation coat". The "substrate" can be a powder or multiparticulate, such a granule, pellet, bead, spherule, beadlet, microcapsule, millisphere, nonocapsule, etc. (page 51, lines 21-25). The "encapsulation coat" contains the pharmaceutical agent and surfactant (page 5, lines 19-21). In McTeigue et al. the "coated particles" are made from "a seed core" (which is predominately "microcrystalline cellulose") and the pharmaceutically active ingredient which is attached to the seed core. However, in the Applicants' Specification and claims, the term "substrate" refers to animal feed. The solid core to which the veterinary active agent is applied is referred to as "carrier material" in the Applicants' Specification and claims. For the Applicants' invention, the solid core (or "carrier material") containing the veterinary active agent and the masking agent are mixed intimately with the substrate or animal feed.

As discussed above, McTeigue et al. does not use microcrystalline cellulose as the animal feed. As discussed above, McTeigue et al. does not discuss intimately mixing McTeigue's coated particles with animal feed. Furthermore, amended Claims 21 and 29 now exclude cellulose as a possible component of the carrier material. Thus, McTeigue et al. fails to teach many aspects of the claims, and it teaches away from using sugar, lactose, saccharose, and starch for the carrier material.

Similarly, Patel et al. does not disclose intimately mixing Patel's "solid carrier" (defined as the combination of the active pharmaceutical agent and the surfactant coating the a bead or other thing) with animal feed. Furthermore, Patel et al. requires the use of surfactants as part of the encapsulation coat (page 5, lines 19-21).

Applicants do **not** use surfactants with the veterinary active ingredient to coat the Applicants' "carrier material". Applicants intimately mix the coated particles with the animal feed ("substrate"). Nothing in either McTeigue et al. or Patel et al. teach mixing the things that are covered with the veterinary active ingredient and a masking layer with a "substrate" that is "animal feed". As such, these two prior art documents combined do not teach the invention. Nor does the addition of Gasson et al. and Kitamura et al. make up for the omissions of McTeigue et al. and Patel et al., especially regarding Claims 26 and 34 (remember, Claim 28 involves benazipril, not lysed yeast, and should have been combined with the rejection using McTeigue et al. alone (above)).

While the Examiner argued that "Gasson et al. discloses method in which bacteria can be lysed with a lysine [sic] including any kind of food for example, animal food such as pet food, or cattle food as described above...", the Applicants believe that the Examiner failed to understand the teachings of Gasson et al. and that Gasson et al is not relevant prior art.

Gasson et al. describes a lysin (a bacteriophage enzyme that lyses bacteria) to kill bacteria that live on the surface of things, such as food and skin and methods of using lysin to kill bacteria. In other words, Gasson et al. is about disinfecting things with bacteria on them (whether the "thing" is food or skin or otherwise). By disinfecting things, one can, hopefully, prevent infections or reduce undesirable flavors, odors, etc. See Column 1, lines 22-24, 25-28, and 41-44; and Column 2, lines 41-45. While Gasson et al. discloses that bacteria in food (human or animal food) can be lysed with lysin. By destroying bacteria via lysis, one can prevent illness or soiling of the food.

Gasson et al. is NOT relevant prior art. The claimed invention involves medicine for animals that contain the veterinarian active ingredient on small particles which are then coated to mask the taste of the veterinarian active ingredient. These coated particles are intimately mixed with a "substrate" (animal feed). The resultant mixture is made into tablets or pellets for administration to the animal. Claims 26 and 34 for which Gasson et al. is cited adds the limitation that the animal feed is lysed yeast. Yet, Gasson et al. is about disinfecting things covered with bacteria by using lysin to kill the bacteria. Just because lysin "lyses" the bacteria, Gasson et al. is not relevant to "lysed" yeast as the animal feed.

Furthermore, Claims 26 and 34 now read on yeast, not lysed yeast. Thus, Gasson et al. fails to qualify as prior art.

The Applicants agree with the Examiner that Kitamura et al. (U.S. Patent 3,917,510) discloses methods of killing yeast by lysis and discloses that lysed yeast may be useful in the food and feed industries. However, the relevance of Kitamura et al. to the claimed invention is questioned by the Applicants. Whereas Kitamura et al. discloses that lysed yeast may be useful in the feed industry, Kitamura et al. does not disclose that lysed yeast may be useful in a

medicinal tablet or pellet for animals. The feed industry and the veterinary medicinal industry are two distinct and separate industries. One of ordinary skill in the art of one would not be knowledge about the other. Thus, the Applicants believe that Kitamura et al. is not relevant or analogous prior art for the claimed invention, nor would one of ordinary skill in the art of veterinary medicinal industry would think to combine Kitamura et al. with prior art of pharmaceuticals.

Furthermore, Claims 26 and 34 now read on yeast, not lysed yeast. Thus, Kitamura et al. fails to qualify as prior art.

Even if one assumes that there is a reason to combine the disclosures of McTeigue et al., Patel et al., and Kitamura et al., these prior art still do not teach the invention in Claims 26 and 34. Kitamura et al. does not teach that one can mix the coated particles with yeast and make into a pellet or tablet. Patel et al. and McTeigue et al. have as a basic deficiency the lack of teaching that one can combine their "pharmaceutical coated particles" with animal feed, much less with yeast. And Kitamura et al. fails to add that additional component. McTeigue et al. teaches away from the claimed invention. Patel et al., Kitamura et al., and Gasson et al. fail to counteract that teaching.

Because of the previous discussion, the Applicants respectfully request that the Examiner withdraw these two rejections under § 103(a).

"Response to Arguments" Section

In the "Response to Arguments" section, the Examiner states that the Applicants' arguments and amendments filed on November 14, 2005 have been considered but are not persuasive. The Examiner notes that the Applicants stated that Patel et al. disclosed using surfactants and that the claimed invention lacks surfactants. Then the Examiner discussed McTeigue et al. and claims that the teachings of McTeigue et al. teaches these limitations.

As discussed above, McTeigue et al. fails to teach the mixing of the coated particles with a substrate, the substrate being animal feed. Furthermore, the carrier material is limited to lactose, saccharose, starch, and sugar. McTeigue et al. teaches away from these materials as the carrier material. Patel et al. also fails to teach the mixing of its coated particles, called "solid carrier", with animal feed. As such, there is no teaching in either Patel et al. or McTeigue et al. that remedies this deficiency. Thus, the combination of Patel et al. and McTeigue et al. fails to teach the limitation of the claims.

Applicants respectfully request that the Examiner withdraw the prior rejection of the claims.

The Applicants believe that all claims are allowable and respectfully request that the Examiner withdraw all rejections of the claims and allow the claims.

The undersigned left several messages with the Examiner, requesting a phone interview. Because of the complexity of this patent application and the prior art, the undersigned believes that a phone interview would be very useful for the progression of this case. The Examiner did not return the undersigned's phone calls. The undersigned kindly requests that the Examiner arrange a phone interview with the undersigned prior to issuing the next communication.

Respectfully submitted,

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